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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669.883	09/23/2003	Scott Manalis	0492611-0510 ( MIT 10443)	2224
24280	7590	08/19/2004	EXAMINER	
Choate, Hall & Stewart Exchange Place 53 State Street Boston, MA 02109			LUM. LEON YUN BON	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/669,883	<b>Applicant(s)</b> MANALIS ET AL.	
	<b>Examiner</b> Leon Y Lum	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-160 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-160 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-46 and 97, drawn to an apparatus for detecting an analyte, classified in class 422, subclass 57.
  - II. Claims 47-96 and 98-107, drawn to an apparatus for detecting an analyte, classified in class 422, subclass 68.1.
  - III. Claims 108-127, drawn to a method of fabricating a functionalized microfluidic channel, classified in class 435, subclass 288.2.
  - IV. Claims 128-139, drawn to a method of packaging a device, classified in class 422, subclass 50.
  - V. Claims 140-150, drawn to a method of packaging a device, classified in class 422, subclass 82.01.
  - VI. Claims 151-160, drawn to a method of packaging a device, classified in class 505, subclass 413.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

Art Unit: 1641

806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group I is a device that includes the limitation of one or more detectors for measuring a change in the one or more beams upon binding or reaction of the analyte, which is a limitation that is missing from the device of Group II. Group II is a device that includes the limitation of a sample fluid channel connected to the inlet of at least one of the microfluid channel, which is a limitation that is missing from the device of Group I.

Therefore, Groups I and II have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.

4. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by the materially different processes of lithography and the methods of Groups IV-VI.

This relationship also applies to Groups II and III.

5. Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

Art Unit: 1641

(MPEP § 806.05(f)). In the instant case the product as claimed can be made by the materially different processes of lithography and the methods of Groups III and V-VI.

This relationship also applies to Groups II and IV.

6. Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by the materially different processes of lithography and the methods of Groups III-IV and VI.

This relationship also applies to Groups II and V.

7. Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by the materially different processes of the methods of Groups III-V.

This relationship also applies to Groups II and VI.

8. Inventions III and IV are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

Art Unit: 1641

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group III is a method that includes the step of forming one or more holes in the second channel layer connected to one or more of the trenches, which is a step missing from the method of Group IV. Group IV is a method that includes the step of preparing a poly(dimethyl siloxane) gasket having one or more fluid channels and one or more opening, which is a step missing from the method of Group III.

Therefore, Groups III and IV have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.

9. Inventions III and V are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group III is a method that includes the step of forming one or more holes in the second channel layer connected to one or more of the trenches, which is a step missing from the method of Group V. Group V is a method that includes the step of forming one or more fluid channel and one or more cavities in a substrate, wherein the cavities can be aligned with the microfluidic channels, which is a step missing from the method of Group III.

Therefore, Groups III and V have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.

10. Inventions III and VI are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group III is a method that includes the step of forming one or more holes in the second channel layer connected to one or more of the trenches, which is a step missing from the method of Group VI. Group VI is a method that includes the steps of forming a photoresist on the surface of the patterned substrate and irradiating the photoresist through a mask, thereby removing the photoresist from predetermined areas of the substrate, which is a step missing from the method of Group III.

Therefore, Groups III and VI have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.

11. Inventions IV and V are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group IV is a method that includes the step

Art Unit: 1641

of preparing a poly(dimethyl siloxane) gasket having one or more fluid channels and one or more opening, which is a step missing from the method of Group V. Group V is a method that includes the step of forming one or more fluid channel and one or more cavities in a substrate, wherein the cavities can be aligned with the microfluidic channels, which is a step missing from the method of Group IV.

Therefore, Groups IV and V have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.

12. Inventions IV and VI are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group IV is a method that includes the step of preparing a poly(dimethyl siloxane) gasket having one or more fluid channels and one or more opening, which is a step missing from the method of Group VI. Group VI is a method that includes the steps of forming a photoresist on the surface of the patterned substrate and irradiating the photoresist through a mask, thereby removing the photoresist from predetermined areas of the substrate, which is a step missing from the method of Group IV.

Therefore, Groups IV and VI have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.



Art Unit: 1641

13. Inventions V and VI are unrelated, distinct, and independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions Group V is a method that includes the step of forming one or more fluid channel and one or more cavities in a substrate, which is a step missing from the method of Group VI. Group VI is a method that includes the steps of forming a photoresist on the surface of the patterned substrate and irradiating the photoresist through a mask, thereby removing the photoresist from predetermined areas of the substrate, which is a step missing from the method of Group V.

Therefore, Groups V and VI have different modes of operation and different functions that distinguish them as unrelated, distinct, and independent inventions.

14. Because these inventions are distinct for the reasons given above and the search required for each of Groups I-VI is not required for the other Groups, restriction for examination purposes as indicated is proper.

15. In the event that Applicants elect Group I, a species election for each of the following species is also required:

- a. One transport method,
  - i. Pressure from fluid flow, claim 7

Art Unit: 1641

- ii. Electrophoresis, claim 8
- b. One detector,
  - i. Capacitors, claims 15-17 and 31-32
  - ii. Optical lever, claims 18, 33, and 97
  - iii. Laser vibrometer, claim 18
- c. One capture ligand,
  - i. Nucleic acid, claims 19-21 and 34-36
  - ii. Protein, peptide, or PNA, claims 22-23, and 37-38
  - iii. Antigen, claims 24 and 39
  - iv. Lectin, claims 25 and 40
  - v. Carbohydrate, claims 26-27 and 41-42
- d. One measurement method, and
  - i. Conductivity of the microfluidic channel, claim 28
  - ii. Deformation of the beam, claim 29
- e. One depth range
  - i. Between about 100 nm and about 300nm, claim 43
  - ii. Between about 100  $\mu\text{m}$  and about 100  $\mu\text{m}$ , 45

Art Unit: 1641

13. Currently, claims 1-6, 9-14, 30, 44, and 46 are generic. Claims 7-8, 15-29, 31-43, 45, and 97 are subject to species election.

For example, if Applicants elect Group I and species a(i), b(iii), c(iv), d(ii), and e(i), claims 1-7, 9-14, 18, 25, 29-30, 40, 43-44, and 46 comprise the elected claims.

14. In the event that Applicants elect Group II, a species election for each of the following species is also required:

- a. One transport method,
  - i. Pressure from fluid flow, claim 60
  - ii. Electrophoresis, claim 61
  
- a. One detector,
  - i. Capacitors, claims 69-71 and 95-96
  - ii. Optical lever, claim 73,
  - iii. Laser vibrometer, claim 73
  
- c. One capture ligand,
  - i. Nucleic acid, claims 82-84 and 98-100
  - ii. Protein, peptide, or PNA, claims 85-86 and 101-102
  - iii. Antigen, claims 87 and 103
  - iv. Lectin, claims 88 and 104

iv. Carbohydrate, claims 89-90 and 105-106

15. Currently, claims 47-59, 62-68, 72, 74-81, 91-94, 97, and 107 are generic.

Claims 60-61, 69-71, 73, 82-90, 95-96, and 98-106 are subject to species election.

For example, if Applicants elect Group I and species a(i), b(iii), and c(iv), claims 47-60, 62-68, 72-81, 88, 91-94, 97, 104, and 107 comprise the elected claims.

16. A telephone call was made to Stacy Blasberg on 10 August 10, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

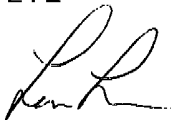
Art Unit: 1641

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

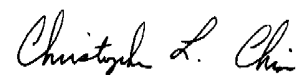
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL



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8/16/04